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August 10, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE-Draft HCV Guidance Document released 6/17/99

Dear Sir/Madam:

The HCV Guidance document submitted for public comment this June presents one significant omission. Omitted is the prior stipulation to lookback 10 years from the HCV positive donation or to January 1988. The consequence of the removal of this stipulation is far-reaching and will necessitate reopening and performing again the current HCV lookback that many institutions, including blood centers and transfusion services, have completed or have underway. This additional requirement to extend lookback for an indefinite will seriously tax an already overburdened health system, with both economic and personnel ramifications. Furthermore, the data from the HCV multi-antigen testing lookback is only now being collated and reviewed. Within our area I can assure you this has been an effort with little yield and we could better serve our transfusion recipients with a general HCV educational effort.

A general HCV education campaign advocating testing for anyone transfused prior to 1992 is in the interest of optimal patient care. In this way we could identify those individuals that received a transfusion from a donor that never returned to the blood center for subsequent donations (and hence test). Due to the lack of funding, the patient (recipient of transfusion) must incur the cost of testing. Benefits of the HCV lookback program can not be truly measured if patients are unable to pay for testing.

When requiring HCV lookback of donors newly identified with HCV infection a "rolling" 10 year period should be employed. In this way we could concentrate our efforts on those recipients at highest risk. Since HCV testing of donor blood began in 1992 most donors possessing antibodies to HCV should have been eliminated from the donor pool and donors within window period will also have been identified.

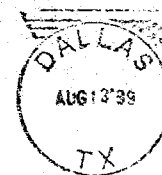
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